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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
09/682,098	07/19/2001	Derek Bernhart	3348.2	5280	
37403 75	90 02/08/2006		EXAM	EXAMINER	
ATTENTION: MICHAEL VERGA			TO, BAOQUOC N		
JAGTIANI + GUTTAG 10363-A DEMOCRACY LANE			ART UNIT	PAPER NUMBER	
FAIRFAX, VA 22030			2162		
			DATE MAILED: 02/08/2004	4	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/682,098	BERNHART ET AL.				
Office Action Summary	Examiner	Art Unit				
	Baoquoc N. To	2162				
The MAILING DATE of this communication a Period for Reply	appears on the cover sheet with	the correspondence address				
A SHORTENED STATUTORY PERIOD FOR REI WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by sta Any reply received by the Office later than three months after the may earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICA 1.136(a). In no event, however, may a repion will apply and will expire SIX (6) MONTH tute, cause the application to become ABAI	ATION. y be timely filed S from the mailing date of this communication. IDONED (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on 11	1/22/2005					
	his action is non-final.					
· <u>·</u>	,—					
closed in accordance with the practice unde	•	•				
Disposition of Claims	·					
4)⊠ Claim(s) <u>1-45</u> is/are pending in the applicati	on.					
4a) Of the above claim(s) is/are withd						
5) Claim(s) is/are allowed.	•					
6)⊠ Claim(s) <u>1-44</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and	d/or election requirement.					
Application Papers						
9) The specification is objected to by the Exami	iner.					
10) The drawing(s) filed on is/are: a) a		the Examiner.				
Applicant may not request that any objection to the	he drawing(s) be held in abeyance	. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the corr	ection is required if the drawing(s)	is objected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the	Examiner. Note the attached (	Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for forei a) All b) Some * c) None of:	gn priority under 35 U.S.C. § 1	19(a)-(d) or (f).				
1. Certified copies of the priority docume	ents have been received.					
2. Certified copies of the priority docume	ents have been received in App	lication No				
3. Copies of the certified copies of the property of the prope	riority documents have been re	ceived in this National Stage				
application from the International Bure	` ' ' '					
* See the attached detailed Office action for a li	ist of the certified copies not re	ceived.				
Attachment(s)	🗂					
1) Motice of References Cited (PTO-892)  Discrete Transport of Draftsperson's Patent Drawing Review (PTO-948)	4) ∐ Interview Sur Paper No(s)/I	nmary (PTO-413) //ail Date				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date		mal Patent Application (PTO-152)				

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#### **DETAILED ACTION**

### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/22/2006 has been entered.

Claims 1, 2, 6-7, 20-22 and 27, 29 and 36 are amended and claim 45 is newly added in the amendment filed on 11/22/2006. Claims 1-45 are pending in this application.

#### Response to Arguments

2. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1-38 and 45are rejected under 35 U.S.C. 103(a) as being unpatentable over Jonathan Wingfield, (Essay Explorer and a "Typical" Experiment, Molecular

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Correction Winter 2000, pages 290-23) in view Maslyn et al. (US. Patent No. 6,408,308 B1).

Regarding on claim 1, Wingfield teaches a method for managing biological information related to a biological experiment comprising:

Acquiring one or more biological values of the biological information using a probe array to conduct the biological experiment (table 1, 2, and 3 shows biological values collected from the plates) (page 2);

Generating a data template including one or more identifiers related to the use of the probe array (fig. 1 shows a generating a template) (page 21);

Specifying in the data template the one or more identifiers related to the use of the probe array (fig. 1, shows Plate and plate id) (page 21);

Receiving in the data template the one or more biological values for at least one or more identifiers in accordance with the one or more biological attributes (table 1, 2 and 3 show data collection the plates) (page 21).

Wingfield discloses generating template to store biological experiment. Wingfield does not explicitly the acquired one or more biological value information using a probe array; however, Maslyn discloses "the expression database 32 has many tables 60 storing information including biologicals 86, samples 88, data source 90, microarray chip design 94 hybridization 96, donor 98 and the like" (col. 4, lines 36-39). In addition, Maslyn also discloses "in step 252, one of the client system receives the raw expression data 140 (FIG. 4B) from the microarray reader/analyzer in the form of a file. In step 254, the system executes the driver procedure 72 (FIG. 4B) to generate flat files, called

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Processed MicroArray Data (PMD) files, from the raw expression data...) (col. 5, lines 60 to col. 6, lines 32). Furthermore, Maslyn also "FIG. 7A through 7K depict a data model for a representation set of tables and fields of expression database 32 of the present invention. Each table is represented by a block with name of the table listed above the block such as "PMDData Source table." The tables store records. The table stores data for each record in the fields which are listed below each table name. The field name also describe the information stored in the field..."(col. 6, lines 61 to col. 8, lines 1-3). Maslyn discloses database tables for storing the acquired data from the microarray. Therefore, it would have been obvious to one ordinary skill in the art at the time of the invention was made to modify Wingfield's system to include the data table for storing the acquired data from the microarray as taught Maslyn in order to provide storage for storing experimental data.

Regarding on claim 2, Wingfield teaches (e) storing the one or more biological values for the at least one or more identifiers in a data structure (table 2, page).

Regarding on claim 3, Wingfield teaches the data structure is included in a database (page 22, fig. 1).

Regarding on claims 4 and 30, Wingfield teaches the one or more identifiers comprise experiment identifiers and the data templates comprise an experiment data template (page 22, fig. 1).

Regarding on claims 5 and 31, Wingfield teaches the one or more identifiers comprise sample identifiers (page 21, fig. 1, plate id) and the data template comprises a sample data template (page 22, fig. 1, experimental layout).

Regarding on claims 6 and 32, Wingfield teaches the data structure comprises an experiment information file for storing the biological information related to the biological experiment (select the data file, page 22, fig. 1).

Regarding on claim 7, Wingfield teaches displaying, prior to receive the biological values for one or more identifier, the data template to a first user (after the selecting of the experimental layout, the template display to the first selector) (page 22, fig. 1).

Regarding on claim 8, Wingfield teaches the value is provided by the first user responsive to displaying the data template (assign the values to different well) (page 22, first column, lines 34-35).

Regarding on claim 9, Wingfield teaches the value is provided by the first user in accordance with a first type attribute (page 21, fig. 1, shows the first user define the attributes types).

Regarding on claim 10, Wingfield teaches the first type attribute is a data attribute, time attribute, integer attribute, floating point, data attribute, character string attribute, required attribute, or controlled attribute (page 21, fig. 1).

Regarding on claim 11, Wingfield teaches the value is provided by the first user in accordance with a required attribute (scientists to assign values to different wells) (col. 1, lines 34-35).

Regarding on claim 12, Wingfield teaches the required attribute specifies that the value is either required or not required to be received (page 21, fig. 1, values are required).

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Regarding on claim 13, Wingfield teaches the value is provided by the user in accordance with a controlled attribute (20 is the control attribute) (page 21, fig. 1).

Regarding on claim 14, Wingfield teaches the controlled attribute specifies that the value is to be one or more of a plurality of user-specified values specified by a second user (one or more scientist can change or assign the value for the wells) (page 22, lines 1-35).

Regarding on claim15, Wingfield teaches the first and second users are different users (one of more scientists are two different person) (page 22, lines 6-9).

Regarding on claims 16 and 36, Wingfield do not explicitly teaches (f) storing instrument information for at least one instrument in the data structure, wherein the instrument is included in the biological experiment related to the probe array. However, Maslyn discloses database 32 has many tables 60 storing information including biological 63, sample 88, data source 90, transcript 92, microarray design 94 hybridization 96, and donor 98 and the like" (col. 4, lines 36-39). This teaches claimed limitation. Therefore, it would have been obvious to one ordinary skill in the art at the time of the invention was made to modify Wingfield's system to include storing instrument information as taught by Maslyn in order to allow other user to known the results and the equipments which use to conduct the experiment.

Regarding on claims 17 and 37, Wingfield teaches (f) storing image in the data structure, wherein the image data is based, at least in part, on scanning of the probe array (page 23, third column, lines 15-16).

of:

Regarding on claims 18 and 38, Wingfield teaches (g) analyzing the image data to generate results data (page 23, third column, lines 15-16); and

(h) storing the results data in the data structure (page 23, third column, lines 15-16).

Regarding on claim 19, Wingfield teaches (i) tracking the value, the image data, and the result data (page 23, third column, lines 17-25).

Claim 20 is rejected under the same reason as to claim, in addition, Wingfield also discloses receiving from a first user a selection of a first user a selection of a first data template having a plurality of selected identifiers each identifying an attributes of the biological experiment (choose the experimental layout) (page 2, fig. 1); saving the biological values in a data structure (store 3D experimental data) (page 23, third column, lines 15-16).

Regarding on claim 21, Wingfield teaches the receiving step comprise the steps
(1) displaying a list of names of plurality of data templates (page 22, fig. 1); and

(2) receiving from the first user, a selection of one of the displayed list of name a name of the first data template (choose the experimental layout) (page 22, fig. 1).

Regarding on claim 22, Wingfield teaches the plurality of data templates include one or more default data templates (choose the experimental layout) (page 22, fig. 1).

Regarding on claim 23, Wingfield teaches the list of names is displayed to the first user in a tree structure of a graphical user interface (page 22, fig. 1).

Regarding on claim 24, Wingfield teaches the data structure includes an experiment information file (page 22, fig. 1).

Regarding on claim 25, Wingfield teaches the experiment information file is included in a database (page 22, col. 1, lines 25-28).

Regarding on claim 26, Wingfield teaches (e) generating the first data template based, at least in part, on a second user specifying the plurality of identifiers (the data template is generated based on one more user) (page 22, fig. 1).

Regarding on claim 27, Wingfield teaches generating the first template based, at least in part, on a second user specifying the attributes of the plurality of identifiers (one or more scientist in the group can load and the previously experiment and change the or assign the value for the wells (page 22, lines 1-35).

Regarding on claim 28, Wingfield teaches the first and second users are different users (one or more scientists are two different person) (page 22, lines 6-9).

Claim 29 is rejected under the same reason as to claim 1.

Regarding on claim 33, Wingfield discloses the computer program product of claim 29, wherein specifying at least one of the one or more identifiers (page 21, fig. 1)

Regarding on claim 34, Wingfield teaches a template generator generates the data template in response to a first user specifying at least one attribute of the one or more identifiers (page 21, fig. 1).

Regarding on claim 35, Wingfield teaches the data template is selected by a second user (page 23, first column, lines 1-7).

4. Claims 39-44 rejected under 35 U.S.C. 103(a) as being unpatentable over Blevins (US. Patent No. 5,594,858) in view Maslyn (US. Patent No. 6,408,308 B1).

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A computer-readable storage medium (memory) (col. 5,lines 60-67);

A database (library 11) (col. 6, line1);

A data template generator (template generator 124) coupled to the computerreadable storage medium (col. 7, lines 18-20); and

An experiment manager (control template system) coupled to the computer readable storage medium and the database (col. 7, lines 18-20),

Wherein the data template generator generates at least one user-defined data template (selects the type of control template to be created) and stores (save) the user-defined data template on the computer-readable medium (col. 12, lines 1-5), each user-defined data template defining attributes of a set of user-selected experiment identifiers (col. 11, lines 10-15), a data template being selected from the at least one user-defined data template (a list of predefined or existing templates) (col. 12, lines 1-5) by a user using the experiment manager, experiment identifiers being input (list of data prompts) (col. 10, lines 1-4) using the experiment manager according to the selected data template, the inputted experiment identifiers being stored in the database as an experiment information file (save) (col. 17, lines 34-36).

Blevins discloses generating template to conduct experiment. However, Blevins does not disclose the claimed experiment is the probe array experiments. On the other hand, Maslyn discloses "the expression database 32 has many tables 60 storing information including biologicals 86, samples 88, data source 90, microarray chip design

94 hybridization 96, donor 98 and the like" (col. 4, lines 36-39). In addition, Maslyn also discloses "in step 252, one of the client system receives the raw expression data 140 (FIG. 4B) from the microarray reader/analyzer in the form of a file. In step 254, the system executes the driver procedure 72 (FIG. 4B) to generate flat files, called Processed MicroArray Data (PMD) files, from the raw expression data...) (col. 5, lines 60 to col. 6, lines 32). Furthermore, Maslyn also "FIG. 7A through 7K depict a data model for a representation set of tables and fields of expression database 32 of the present invention. Each table is represented by a block with name of the table listed above the block such as "PMDData Source table." The tables store records. The table stores data for each record in the fields which are listed below each table name. The field name also describe the information stored in the field..." (col. 6, lines 61 to col. 8. lines 1-3). Maslyn discloses the experiment using microarray. And the generated template in Blevins can be used to conduct Maslyn's experiment. Therefore, it would have been obvious to one ordinary skill in the art at the time of the invention was made to modify Wingfield's system to include microarray for use in the experiment as taught Maslyn in order to generate template to conduct a biological experiment using the microarray.

Wingfield discloses generating template to store biological experiment. Wingfield does not explicitly disclose the acquired one or more biological value information using a probe array; however, Maslyn discloses "the expression database 32 has many tables 60 storing information including biologicals 86, samples 88, data source 90, microarray chip design 94 hybridization 96, donor 98 and the like" (col. 4, lines 36-39). In addition,

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Maslyn also discloses "in step 252, one of the client system receives the raw expression data 140 (FIG. 4B) from the microarray reader/analyzer in the form of a file. In step 254, the system executes the driver procedure 72 (FIG. 4B) to generate flat files, called Processed MicroArray Data (PMD) files, from the raw expression data...) (col. 5, lines 60 to col. 6, lines 32). Furthermore, Maslyn also "FIG. 7A through 7K depict a data model for a representation set of tables and fields of expression database 32 of the present invention. Each table is represented by a block with name of the table listed above the block such as "PMDData Source table." The tables store records. The table stores data for each record in the fields which are listed below each table name. The field name also describe the information stored in the field..."(col. 6, lines 61 to col. 8, lines 1-3). Maslyn discloses database tables for storing the acquired data from the microarray. Therefore, it would have been obvious to one ordinary skill in the art at the time of the invention was made to modify Wingfield's system to include the data table for storing the acquired data from the microarray as taught Maslyn in order to provide storage for storing experimental data.

Regarding on claim 40, Blevins teaches instrument information is included in the experiment information file (col. 17, lines 25-35).

Regarding on claim 41, Blevins teaches a data processor couple to the database, for acquiring experiment data and storing the experiment data as an experiment data file in the database, a data analyzer, connected to the database, for analyzing result files in the database; and

A file manager (the control template library) for tracking the experiment file, the experiment data file, and analyzing results files (col. 7, lines 18-19).

Regarding on claim 42, Blevins teaches the experiment data file is an image file (col. 17, lines 25-35).

Regarding on claim 43, Blevins teach the file manager tracks the experiment information file, the experiment data file, and the analyzed results files according to the files names (col. 12, lines 18-37).

Regarding on claim 44 is rejected same as claim 39, in addition Blevins also teaches a computer-readable storage medium having at least one default data table stored thereon (predefined or existing templates) (col. 12, lines 1-5).

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- Claim 45 is rejected under 35 U.S.C. 102(e) as being anticipated by Essay
   Explorer and a "Typical" Experiment, Molecular Correction Winter 2000, pages 290-23)

Regarding on claim 45, Wingfield discloses a method information when performing a biological experiment on a biological sample comprising:

Generating an experimental data template including one or more experimental identifiers that are specified as having one or more experimental attribute (page 21, fig. 1);

Generating a sample data template including one or more sample identifiers related to the biological sample, wherein the one or more sample identifier are specified as having one or more sample attributes (generating 10-15 different plate layouts in the course of testing an experiment) (page 23, first column, lines 21-23);

Storing the experimental data template and sample data template on a storage medium (data retrieved different run, one run one of the experiment data temple and other run can be sample data template) (page 23, first column, lines 27-29);

Inputting into an experimental manager at least one experimental value and at least one sample value (scientists can quickly tweak a layout (experimental manager) and can readily compare the data retrieval from different run) (page 23, first column, lines 27-29), wherein the at least one experimental value is inputted by retrieving the experimental data template and receiving in the experimental data template the one or more experimental for at least of one or more experimental identifier in accordance with the one or more experimental attributes (page 21, fig. 1), and wherein the at least one sample value is inputted by retrieving the sample data template and retrieving in the sample data template the one or more sample values for at least one of the one or more sample identifiers in accordance with the one or more sample attributes (page 21, fig. 1); and

Capturing instrument operational values directly from at least one instrument used to conduct the biological experiment by the experiment manager (a layout can compare retrieve different run wherein each run obtains the data from the wells plates) (page 23, first column, lines 27-29).

#### Contact Information

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baoquoc N. To whose telephone number is at 571-272-4041 or via e-mail Baoquoc N. To@uspto.gov. The examiner can normally be reached on Monday-Friday: 8:00 AM – 4:30 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Breene can be reached at 571-272-4107.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks Washington, D.C. 20231.

The fax numbers for the organization where this application or proceeding is assigned are as follow:

(571) –273-8300

[Official Communication]

BQ To

Feb 3rd, 2006

PRIMARY EXAMINER